

#### Remarks

Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39 and 41 are pending in the subject application. By this amendment, Claims 1 and 41 have been amended and Claim 87 has been added. Applicants maintain that the amendments to Claims 1 and 41 do not raise an issue of new matter. Support for the claim amendments can be found in the specification at, *inter alia*, page 22, lines 6-9, page 22, line 28 to page 23, line 6, page 24, lines 27-29, and page 28, lines 24-27. Support for new Claim 87 can be found in the specification at, *inter alia*, page 22, lines 6-9. Applicants have also made minor changes to the specification and figures in order to correct certain formalities. Applicants maintain that these amendments raise no issue of new matter. Accordingly, entry of the amendments is respectfully requested.

#### Objections to the Specification

The Examiner objected to the specification because of numerous formalities. In response, applicants have amended the specification herein to correct these formalities. Accordingly, applicants maintain that the objections to the specification have been obviated.

#### Objections to the Drawings

The Examiner objected to Figures 1, 2, 3, 4, 5, 6, 18 and 25 because of numerous formalities. In response, applicants have replaced Figures 1, 2, 3, 4, 5, 6, 18 and 25 with replacement Figures 1, 2, 3, 4, 5, 6, 18 and 25. Accordingly, applicants maintain that the objections to the drawings have been obviated.

#### Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39 and 41 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject

Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardanov, Vasan Sambandamurthy and Sheldon Morris  
Appl. No.: 10/542,958  
Filed: January 30, 2007  
page 29 of 31

matter which applicants regard as the invention. The Examiner indicated that the claims, which are drawn to a method for treating a mammal which does not have combined immune deficiency, but is deficient in CD4<sup>+</sup> or CD8<sup>+</sup> lymphocytes, by inoculating the mammal with attenuated mycobacterium is unclear because the claims do not recite any disease, disorder or condition for which the animal is being treated.

In response, applicants note that Claims 1 and 41, as amended, do not recite a method of treating a mammal, but rather a method for inoculating a mammal against a *Mycobacterium tuberculosis* (*M. tuberculosis*) complex. Accordingly, applicants respectfully maintain that amended Claims 1 and 41, as well as dependent claims 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38 and 39, do particularly point out and distinctly claim the subject matter which applicants regard as the invention. Reconsideration and withdrawal of this rejection are respectfully requested.

#### Supplemental Information Disclosure Statement

This Information Disclosure Statement is being filed to supplement the Information Disclosure Statement filed on July 6, 2006 in connection with the above-identified application.

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant would like to direct the Examiner's attention to the references that are listed on Form PTO/SB/08A (1 page) and PTO/SB/08B (1 page) and attached hereto. Applicants note that unpublished U.S. Patent Application Nos. 11/794,506, 11/794,372, and 11/794,373 are based on PCT International Application Nos. WO 2006/076519, WO 2006/076517, and WO 2006/076343, respectively. Copies of these PCT applications are listed on the enclosed Form PTO/SB/08A and attached hereto.

Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardanov, Vasan  
Sambandamurthy and Sheldon Morris  
Appl. No.: 10/542,958  
Filed: January 30, 2007  
page 30 of 31

Applicants are submitting the subject Supplemental Information Disclosure Statement pursuant to 37 C.F.R. §1.97(c)(2) before the mailing of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application. A check for \$180.00 is enclosed to cover the fee for submitting an Information Disclosure Statement pursuant to 37 C.F.R. §1.97(c)(2).

#### CONCLUSIONS

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the rejections set forth in the April 3, 2008 Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

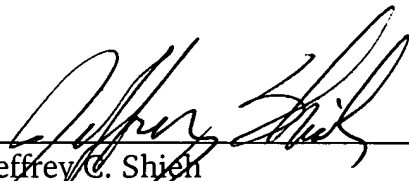
Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardanov, Vasan  
Sambandamurthy and Sheldon Morris  
Appl. No.: 10/542,958  
Filed: January 30, 2007  
page 31 of 31

A check for \$205.00 is enclosed to cover the \$180.00 fee for filing a Supplemental Information Disclosure Statement and the \$25.00 fee for one additional claim over 20. No other fee is deemed necessary in connection with the filing of this Amendment and Supplemental Information Disclosure Statement. However, if any additional fee is required to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Overpayments may also be credited to Deposit Account No. 01-1785.

Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP  
Attorneys for Applicants  
90 Park Avenue  
New York, NY 10016  
(212) 336-8000

Dated: New York, New York  
July 3, 2008

By:   
Jeffrey C. Shieh  
Registration No. 61,862